

## Mississippi Secretary of State

## ADMINISTRATIVE PROCEDURES NOTICE FILING

|   |                          |  |                                  |              |
|---|--------------------------|--|----------------------------------|--------------|
| AGENCY NAME<br>Mississippi State Department of Health |                          | CONTACT PERSON<br>Mitchell Adcock  | TELEPHONE NUMBER<br>601-576-7847 |              |
| ADDRESS<br>570 East Woodrow Wilson Ave.               |                          | CITY<br>Jackson  | STATE<br>MS                      | ZIP<br>39216 |
| EMAIL<br>Ingrid.Williams@msdh.ms.gov                  | SUBMIT DATE<br>2/19/2016 | Name or number of rule(s):<br>Title 15: Mississippi Department of Health Part 4: Office of Health Services<br>Subpart 1: Division of Genetics Chapter 1. NEWBORN SCREENING AND BIRTH DEFECTS<br>REGISTRY Subchapter 1. AUTHORITY<br>Rule 1.1.1. Statutory Authority SOURCE: Miss. Code Ann. §41-21-201<br>Rule 1.1.2. Legal Requirements |                                  |              |

Short explanation of rule/amendment/repeal and reason(s) for proposing rule/amendment/repeal:

Rule: Chapter 1, Subchapter 1. Authority, Rule 1.1.2 Legal Requirement

Specific legal authority authorizing the promulgation of rule: Section 41-21-201 of MS Code

List all rules repealed, amended, or suspended by the proposed rule: Chapter 1, Subchapter 1. Authority, Rule 1.1.2 Legal Requirement

## ORAL PROCEEDING:

☒ An oral proceeding is scheduled for this rule on Date: 3/14/2016 Time: 10:00a.m. Place: Osborne Auditorium, MSDH 570 E Woodrow Wilson, Jackson, MS 39216

☐ Presently, an oral proceeding is not scheduled on this rule.

If an oral proceeding is not scheduled, an oral proceeding must be held if a written request for an oral proceeding is submitted by a political subdivision, an agency or ten (10) or more persons. The written request should be submitted to the agency contact person at the above address within twenty (20) days after the filing of this notice of proposed rule adoption and should include the name, address, email address, and telephone number of the person(s) making the request; and, if you are an agent or attorney, the name, address, email address, and telephone number of the party or parties you represent. At any time within the twenty-five (25) day public comment period, written submissions including arguments, data, and views on the proposed rule/amendment/repeal may be submitted to the filing agency.


## ECONOMIC IMPACT STATEMENT:

☐ Economic impact statement not required for this rule. ☒ Concise summary of economic impact statement attached.

| TEMPORARY RULES  | PROPOSED ACTION ON RULES  | FINAL ACTION ON RULES  |
|--|---|--|
| _____ Original filing<br>_____ Renewal of effectiveness<br>To be in effect in _____ days<br>Effective date:<br>_____ Immediately upon filing<br>_____ Other (specify): _____ | <b>Action proposed:</b><br>_____ New rule(s)<br><u>x</u> _____ Amendment to existing rule(s)<br>_____ Repeal of existing rule(s)<br>_____ Adoption by reference<br><b>Proposed final effective date:</b><br><u>X</u> _____ 30 days after filing<br>_____ Other (specify): _____ | <b>Date Proposed Rule Filed:</b> _____<br><b>Action taken:</b><br>_____ Adopted with no changes in text<br>_____ Adopted with changes<br>_____ Adopted by reference<br>_____ Withdrawn<br>_____ Repeal adopted as proposed<br><b>Effective date:</b><br>_____ 30 days after filing<br>_____ Other (specify): _____ |

Printed name and Title of person authorized to file rules: Mitchell Adcock, Chief Administrative Officer

Signature of person authorized to file rules: Mitchell Adcock

| OFFICIAL FILING STAMP  | DO NOT WRITE BELOW THIS LINE<br>OFFICIAL FILING STAMP  | OFFICIAL FILING STAMP  |
|------------------------|--|------------------------|
| Accepted for filing by | <br>Accepted for filing by<br><u>#21785</u> <u>[Signature]</u> | Accepted for filing by |



DELBERT HOSEMAN  
*Secretary of State*

### CONCISE SUMMARY OF ECONOMIC IMPACT STATEMENT

An Economic Impact Statement is required for this proposed rule by Section 25-43-3.105 of the Administrative Procedures Act. This is a Concise Summary of the Economic Impact Statement which must be filed with the Secretary of State's Office.

|   |   |                                  |
|---|---|----------------------------------|
| AGENCY NAME<br>Mississippi State Department of Health   | CONTACT PERSON<br>Mitchell Adcock   | TELEPHONE NUMBER<br>601-576-7847 |
| ADDRESS<br>570 East Woodrow Wilson Ave.   | CITY<br>Jackson   | STATE<br>MS                      |
| EMAIL<br>Ingrid.Williams@msdh.ms.gov  | ZIP<br>39216  |                                  |
| DESCRIPTIVE TITLE OF PROPOSED RULE<br>Rules and Regulations governing the Newborn Screening Program |   |                                  |
| Specific Legal Authority Authorizing the promulgation of Rule:<br>Section 41-21-201 of MS Code      | Reference to Rules repealed, amended or suspended by the Proposed Rule:<br>Chapter 1, Subchapter 1. Authority, Rule 1.1.2 Legal Requirement |                                  |

#### A. Estimated Costs and Benefits

1. Briefly summarize the benefits that may result from this regulation and who will benefit: **The benefit of approving this rule includes the Newborn Screening program ability to maintain operations of the program as a new test (Pompe) is added to the screening panel. The cost of not adopting the rule to increase fees may result in less qualified staff and the decrease in follow-up services provided to NBS patients and their families.**
2. Briefly describe the need for the proposed rule: **The proposed rule will allow the MS State Department of Health to add additional test and increase fees to support the operation of the Statewide Newborn Screening Program. Currently the program screens approximately 38,000 infants and provides follow-up for infants identified with genetic diseases and disorders.**
3. Briefly describe the effect the proposed action will have on the public health, safety, and welfare: **The Newborn Screening Program provides follow-up for more than 40 genetic conditions. The action supports House Bill 717 Re: NBS conditions and methods for tracking infants identified with genetic conditions. Early identification of genetic conditions, such as Pompe, may result in the improved quality of life and decrease disabilities or even the death of a child.**
4. Estimated Cost of implementing proposed action:
  - a. To the agency  
☐ Nothing ☒ Minimal ☐ Moderate ☐ Substantial ☐ Excessive
  - b. To other state or local government entities  
☐ Nothing ☒ Minimal ☐ Moderate ☐ Substantial ☐ Excessive
5. Estimated Cost and/or economic benefit to all persons directly affected by the proposed rule:
  - c. Cost:  
☐ Nothing ☒ Minimal ☐ Moderate ☐ Substantial ☐ Excessive
  - d. Economic Benefit:  
☐ Nothing ☒ Minimal ☐ Moderate ☐ Substantial ☐ Excessive



6. Estimated impact on small businesses:

☒ Nothing ☐ Minimal ☐ Moderate ☐ Substantial ☐ Excessive

- a. Estimate of the number of small businesses subject to the proposed regulation:
- b. Projected costs for small businesses to comply:
- c. Statement of probable effect on impacted small businesses:

7. The cost of adopting the rule compared to not adopting the rule or significantly amending the existing rule (check option):

☐ substantially less than ☐ moderately less than ☐ minimally less than  
☐ the same as ☐ minimally more than ☒ moderately more than  
☐ substantially more than ☐ excessively more than

8. The benefit of adopting the rule compared to not adopting the rule or significantly amending the existing rule (check option):

☐ substantially less than ☐ moderately less than ☐ minimally less than  
☐ the same as ☐ minimally more than ☐ moderately more than  
☒ substantially more than ☐ excessively more than

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B. Reasonable Alternative Methods

1. Other than adopting this rule, are there less costly or less intrusive methods for achieving the purpose of the proposed rule?

☐ yes ☒ no

2. If yes, please briefly describe available, reasonable alternative(s) and the reasons for rejecting those alternatives in favor of the proposed rule. (Please see §25-43-4.104 for factors you must consider.)

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C. Data and Methodology

1. Please briefly describe the data and methodology you used in making the estimates required by this form. **The methodology for determining the increase in fees includes taking the following associated costs into consideration: laboratory cost for testing of Pompe, and materials necessary for parents and providers to support and maintain a credible screening program.**

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D. Public Notice

1. Where, when, and how may someone present their views on the proposed rule and request an oral proceeding on the proposed rule if one is not already scheduled? **An Oral Proceeding will be held at the Mississippi State Department of Health Osborne Auditorium on March 14th. The meeting will begin promptly at 10:00 a.m.**

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SIGNATURE

*Mitchell Adcock by ADW*

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TITLE

Mitchell Adcock, Chief Administrative Officer

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DATE

February 19, 2016

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PROPOSED EFFECTIVE DATE OF RULE

30 days after filing